Validation of the Cleaning Process

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Contents of the presentation

- Choosing of test soils
- Choosing of markers / test methods
- Contamination process
- Radionuclide method versus OPA method
- Acceptance criteria
- Grouping of instruments
- Performance qualification of W/D
- IFU information to be provided

Choosing of test soils for surgical instruments

The test soil should be chosen in order to represent the typical type of contamination witnessed during a surgical intervention: blood.

Sheep blood is available from controlled production sites and doesn't include any questions related to human ethics.

The blood should be ordered in heparinized mode to prevent coagulation and allow for transport and storage.

Protamine sulfate has to be added to the blood immediately before use to reactivate coagulation for realistic contamination.

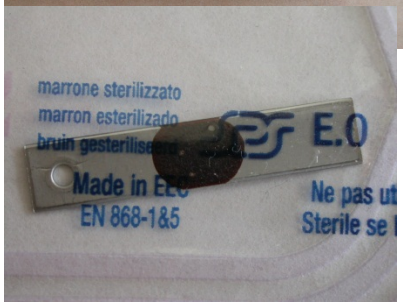
The amount of test soil applied should be realistic because the way the contamination is performed should represent the clinical use of the instruments.

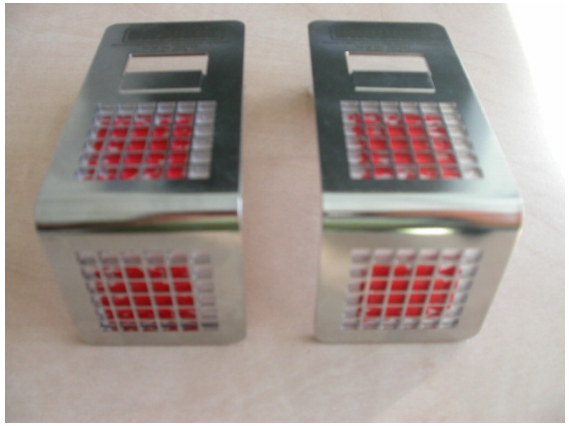
Furthermore the amount of contamination has to represent a worst case scenario.

Which Test Method should be selected?

Swab Test on the instruments?

Cleaning indicators?

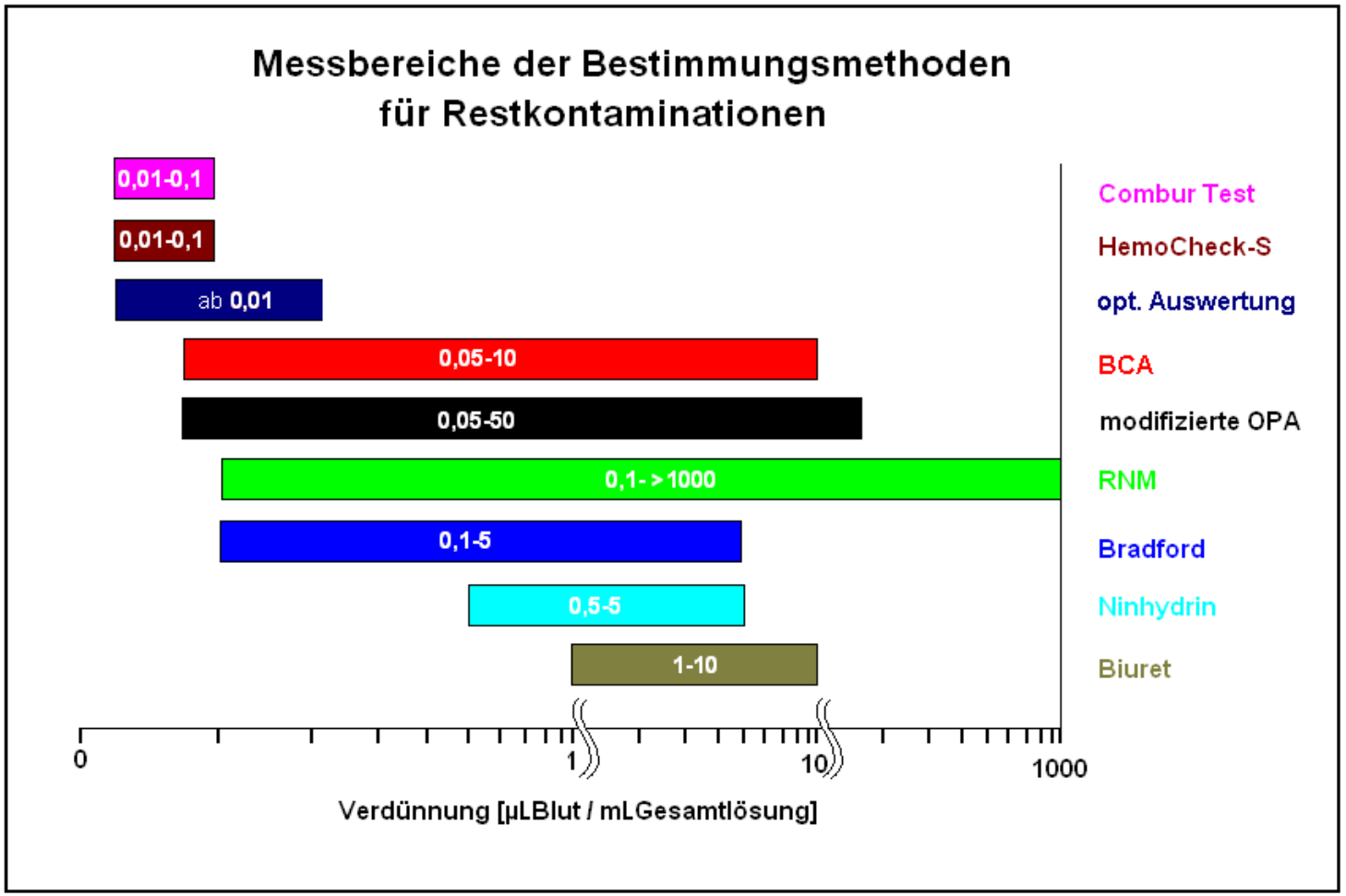




Choosing of markers / test methods

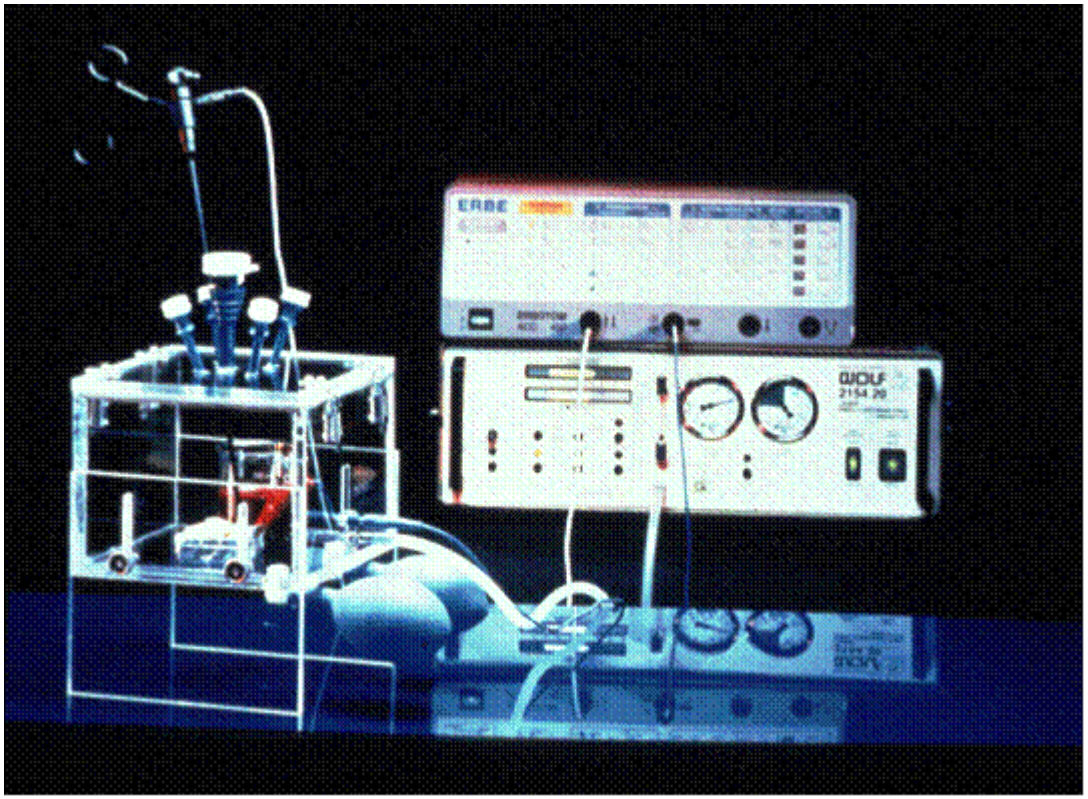
Bradford-Method
Modified OPA-Method
Biuret-Reaction
BCA-Protein Assay Kit
Ninhydrin reaction
ASTM E 2314-03
TOC
ATP test
Combur 9Test
HemoCheck-S
Radionuclide method (RNM)
Photoelectonspectroscopy XPS

Sensitivity of test methods in a dilution series



Contamination process I

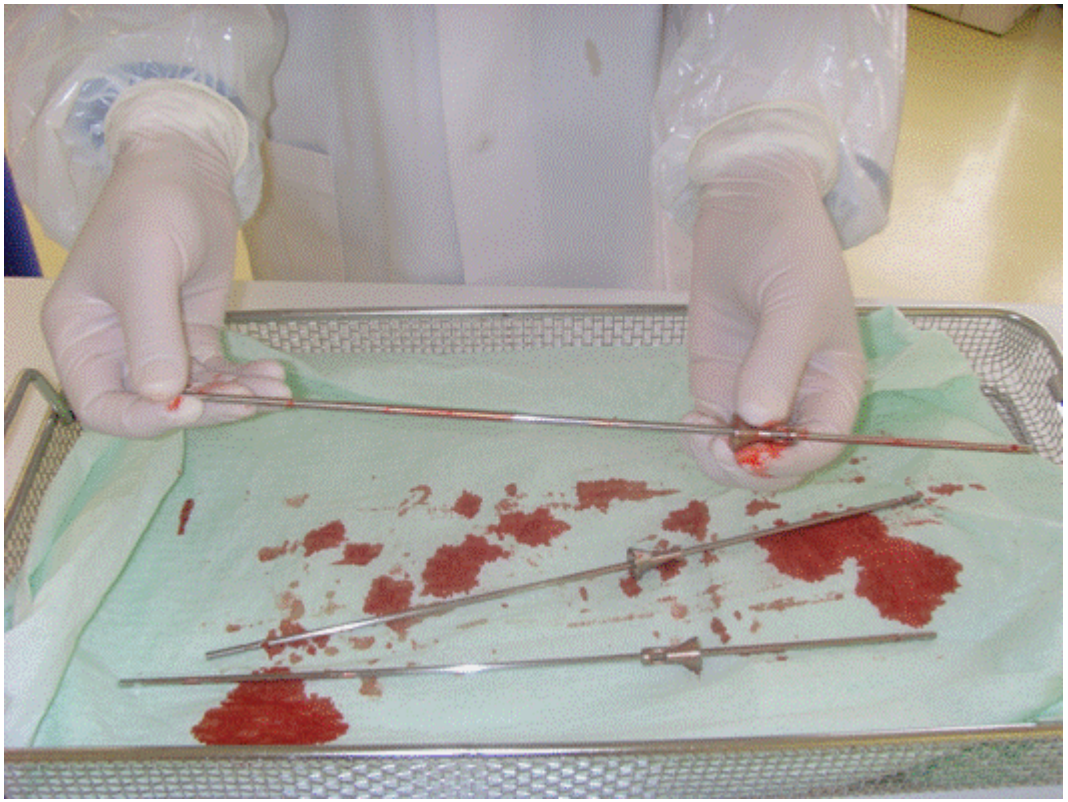
The devices are introduced into the simulation model, the tip of the device is submerged into radioactively labelled blood. The model is insufflated with 15 mm Hg. During the contamination time (5 min) the jaws of the device will be moved.



Insufflation pressure, capillary forces and pump effects lead to inside contamination of the device.

Contamination process II

The instruments are inoculated by touching with heavily contaminated gloves and the sliding part of the instrument is moved back and forth



Radionuclide Method (RNM)

A non destructive test procedure for the validation of the cleaning process of surgical devices with lumens and hidden surfaces;

e.g.

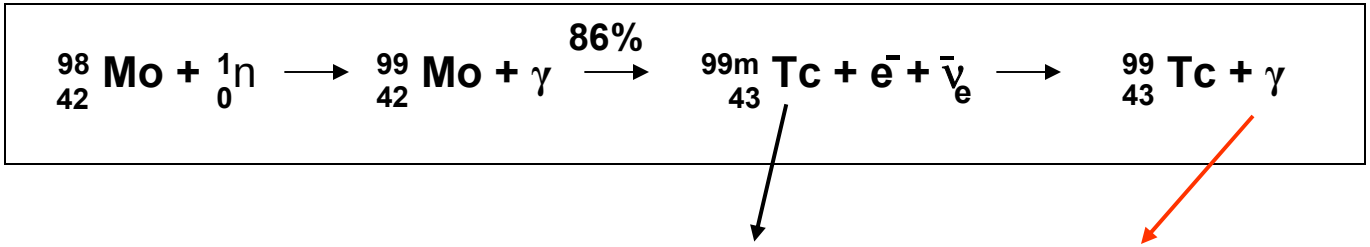
- **forceps and scissors for open surgery**
- **devices for minimally invasive surgery**
- **devices for flexible endoscopy**

Radionuclide Method

- **Radioactive labeling of test soils**
- **Quantification of applied test soil**
- **„Quantification of remaining test soil“**
- **Detection of problematic spots in instruments without destruction**
- **Validation method for cleaning processes**
- **Quality assurance for elution methods**
- **Mentioned in AAMI TIR 30**

Radioactive Marker

Technetium 99^m

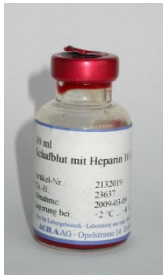


Clinical Use:

<u>Scintigraphy</u> of bones, lung, spleen, liver, kidney etc. since 1960

Test soil for RNM

Technetium 99^{m} is bound to macro aggregated albumins and mixed with sheep blood



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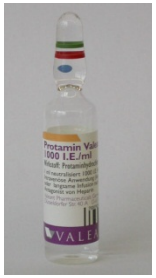


10 ml of test soil contain 100 MBq of radioactivity

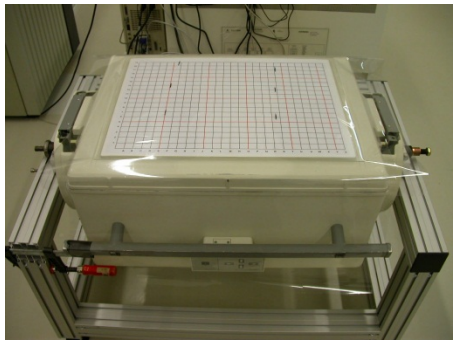
Sheep blood

Tc99m

Protamine sulfate

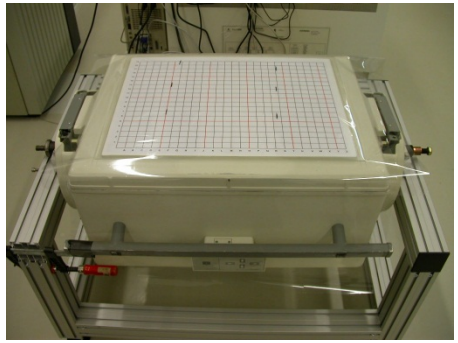
Radionuclide method (RNM)

Contamination of the devices



Measurement before cleaning

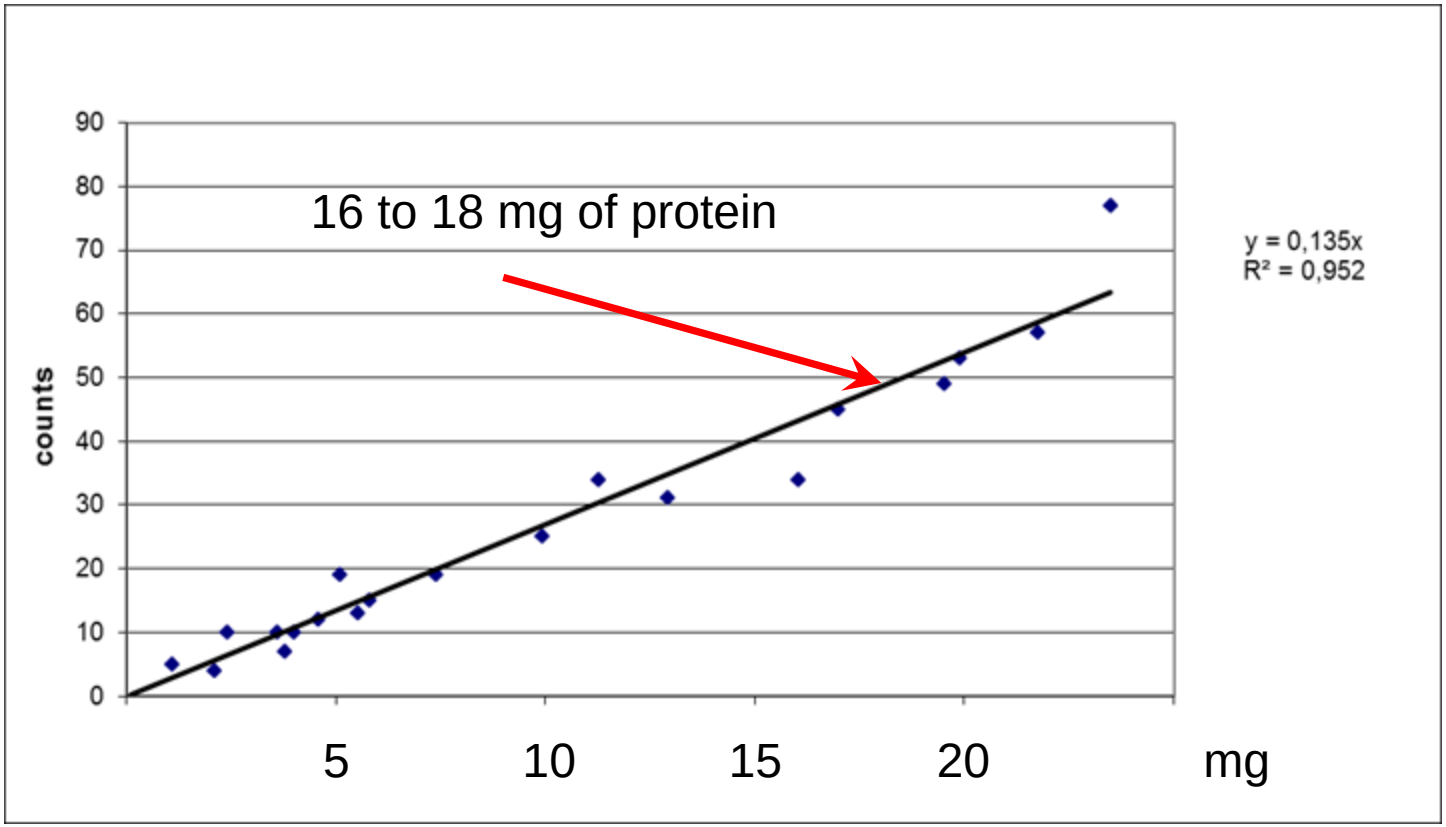
Cleaning of the devices



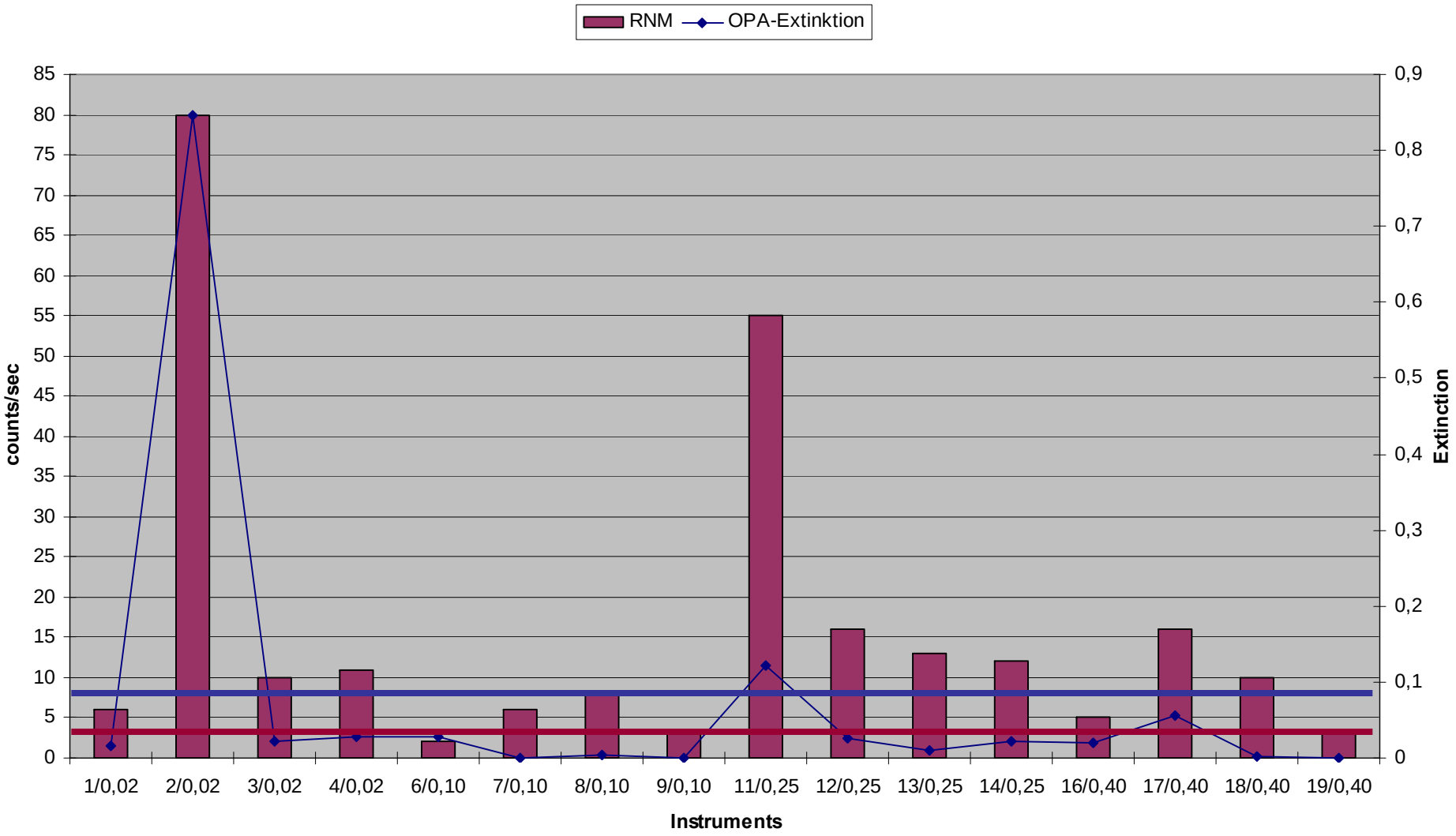
Measurement after cleaning

Analysis

Correlation between counts/s and amount of protein before the cleaning process

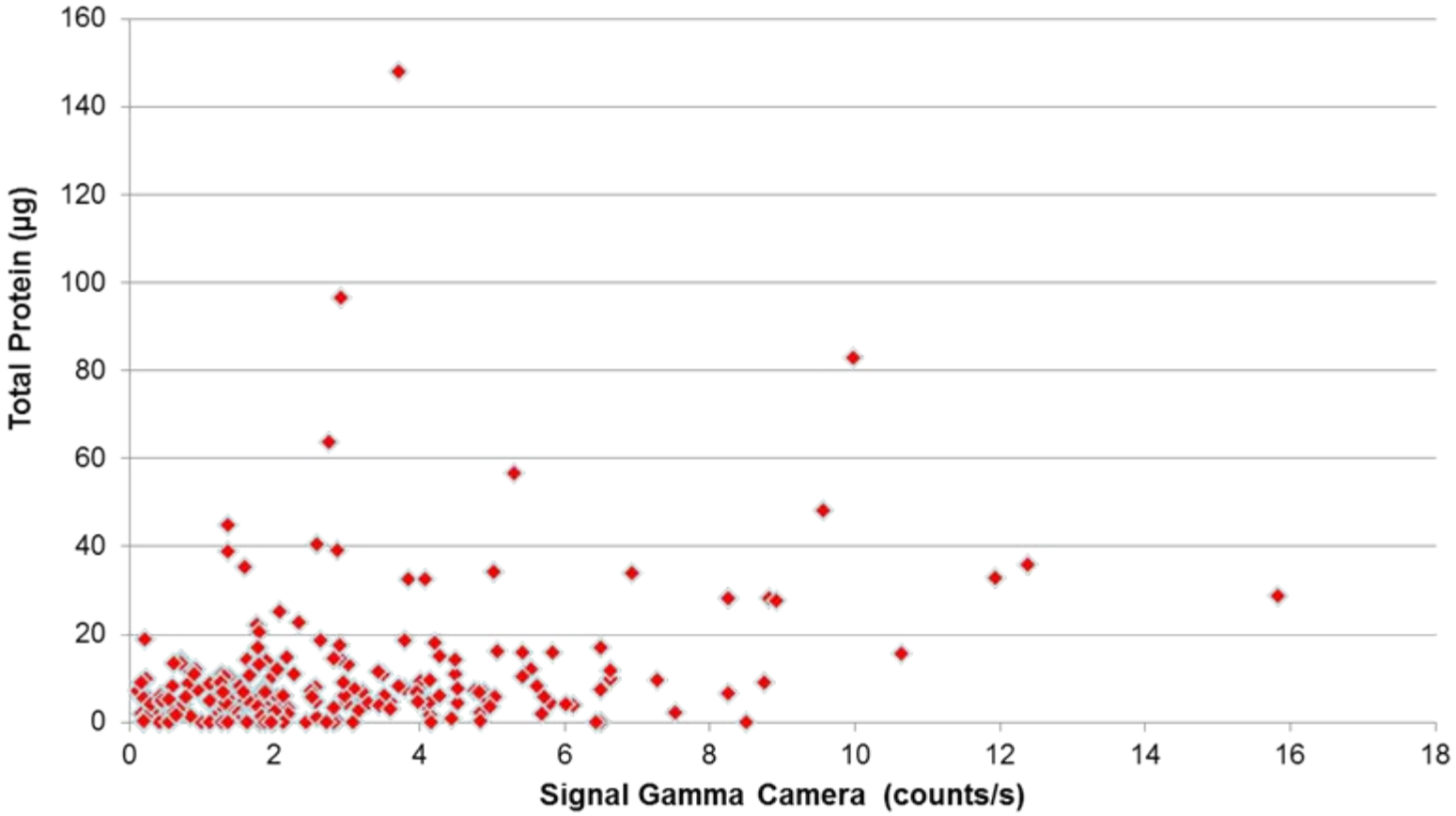


Correlation between RNM- and OPA-Method after the cleaning process

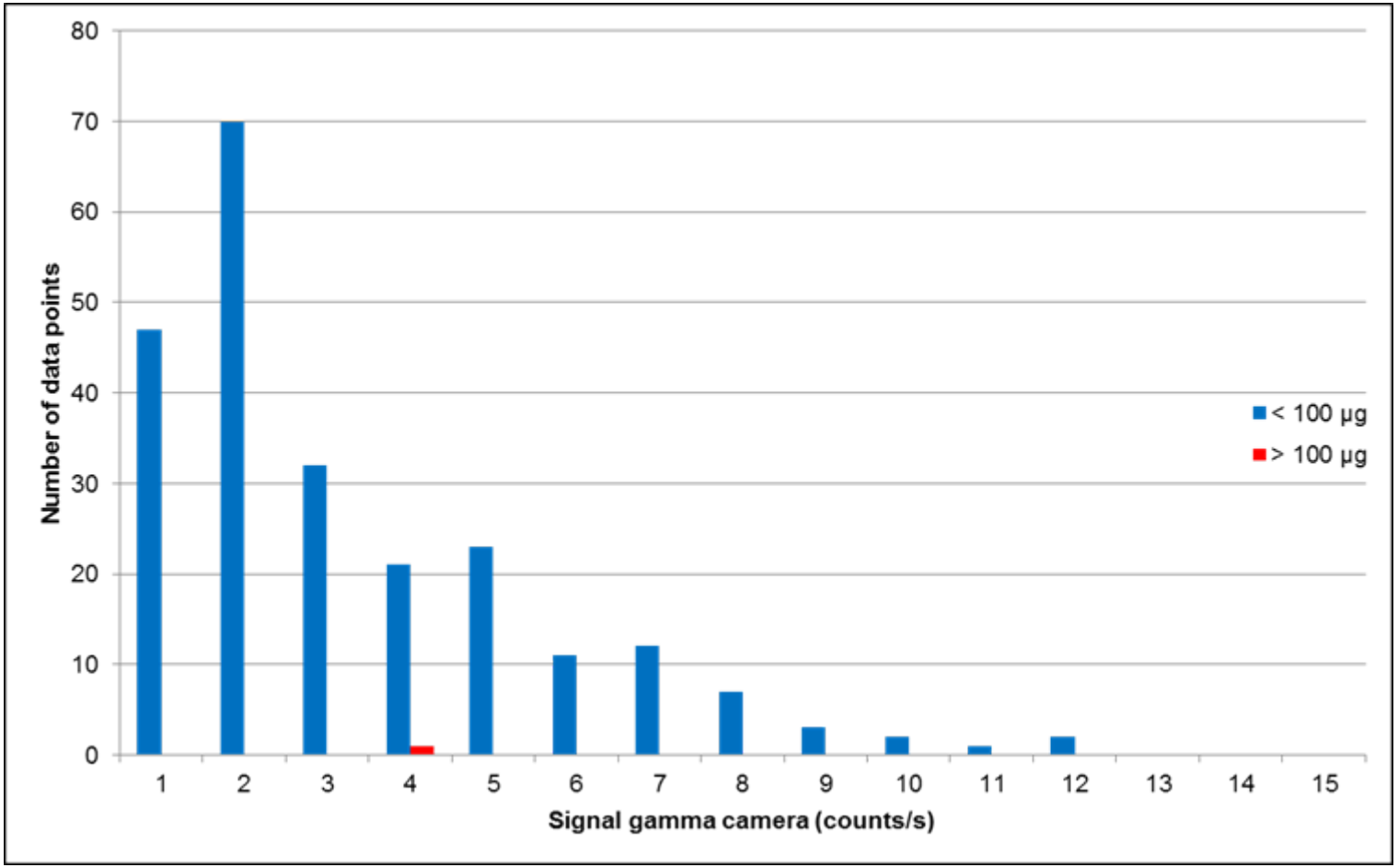


Investigation of Cleaning Performance Following the Standard prEN/ISO 15883-1. Zentr Steril 2005; 13: 34-44

Raw Data for statistical analysis of RNM



Statistical Analysis of RNM



Acceptance criteria

- **At the end of the cleaning process the items shall not show any visual contamination (visual inspection).**

- **Modified OPA-method (EN ISO 15883-1:2006, C2)**

  The total amount of residual proteins on and in the items as determined with the modified OPA method shall be less than 100 µg (warning level) or 200 µg (threshold) corresponding to an extinction value of 0.02

- **USA**

  6.4µg/cm2 whatever is lower.

- **RNM**

  The average cleaning result via the radionuclide method shall be less than or equal to 5 counts per second; the result of a single evaluation shall not exceed 10 counts per second.

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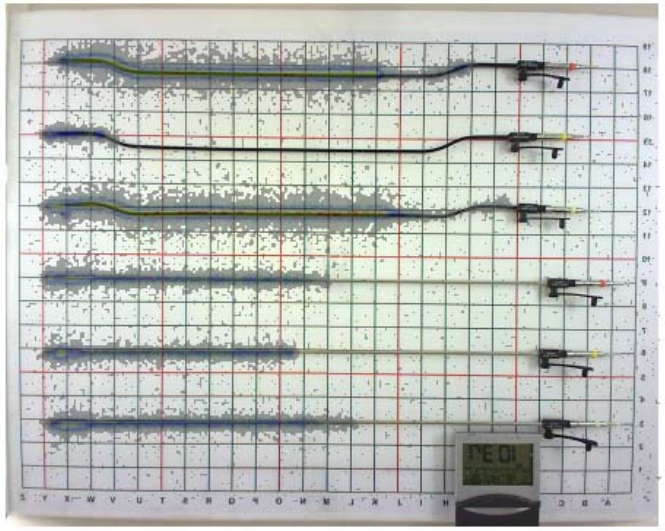

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Project Number - Test Number : 09211-001-1

Aufnahmedatum : 19.05.2011

Kommentar : Run1

Contamination

Name	Pixel	Counts	Zr
RotB	3340	42930	191
GelbB	3818	2452	10
GrünB	3818	51325	228
RotG	3320	9687	42
GelbG	3486	7455	32
RotB	3486	9297	40

Intermediate Measurement 1

Name	Pixel	Counts	Zr
RotB	3340	35704	185
GelbB	3818	604	2
GrünB	3818	34205	177
RotG	3320	3150	15
GelbG	3486	3364	16
RotB	3486	4576	23

Intermediate Measurement 2

Name	Pixel	Counts	Zr
RotB	3340	6214	35
GelbB	3818	325	0
GrünB	3818	3263	18
RotG	3320	1325	6
GelbG	3486	1204	6
RotB	3486	2412	13

Intermediate Measurement 3

Name	Pixel	Counts	Zr
RotB	3340	752	3
GelbB	3818	299	0
GrünB	3818	546	2
RotG	3320	1174	6
GelbG	3486	997	5
RotB	3486	1978	11

FDA Conference
8.-9- June 2011

Silver Springs

Instrument	Color code	After contamination*	After manual pre-cleaning*	After cleaning*	OPA results after cleaning [µg]	After SDS elution*
curved	Red	191	185	35	58	3
curved	Yellow	10	2	0	12	0
curved	Green	228	177	18	26	2
straight	Red	42	15	6	29	6
straight	Yellow	32	16	6	50	5
straight	Green	40	23	13	132	11

EN/ISO 17664

3.5 Cleaning

A validated method of manual cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued.

Where appropriate, at least the following information shall be included:

.accessories required for cleaning process;

.identification and concentration of chemicals required for cleaning;

.identification of water quality,

.limits and monitoring of chemical residues

.limits on temperature, concentration of solution(s), exposure time,

.process temperature(s);

.techniques to be used including rinsing;

Project with 40 instrument manufacturers: Aim of the project

It is the aim of the research project to use the same reprocessing cycle for all kind of instruments.

Enhanced requirements for the cleaning process has to be fulfil by special manual pre-cleaning or special equipement for the pre-cleaning or the w/d.

To many different reprocessing cycles may lead to difficulties in the daily routine and following the specifications.

Standard EN/ISO 17664:

Chapter 5 allows the building of groups of instruments:

„Where the manufacturer supplies a number of different medical devices which share common features and attributes, the validation specified may be performed with respect to these medical devices as a group of family, provided that the manufacturer can demonstrate the commonality of the medical devices and that the tests and assessments address the worst case feature or attribute of the group of family“

Classification of the instruments groups

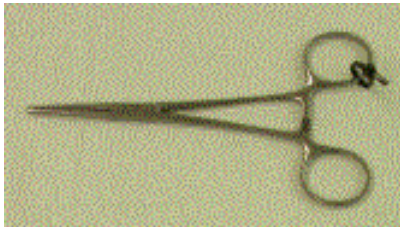
Group 1:	**Critical Instruments,** like hooks
Group 2:	**Critical Instrumentse** Scissors, Clamps
Group 3:	**Shift shaft instruments** Rongeur etc.
Group 4:	**Shaft instruments for MIS** need validation, as the result of the cleaning can not be inspected
Group 5:	**Micro surgical Instruments** need validation, as the result of the cleaning can not be inspected
Group 6:	**Complex Devices** has to be tested, as no analogical conclusions can be made
Group 7:	**Flexible Instruments** need validation, as the result of the cleaning can not be inspected

Classification in Groups

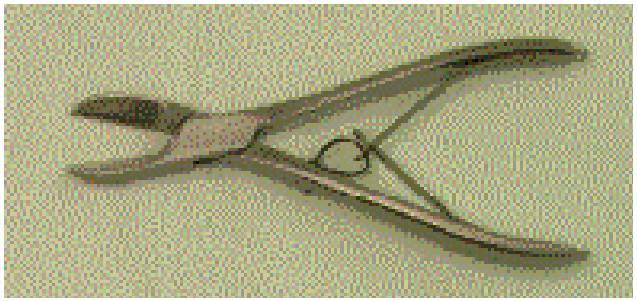
Group 2: Forceps and Scissors

Sub-classification:

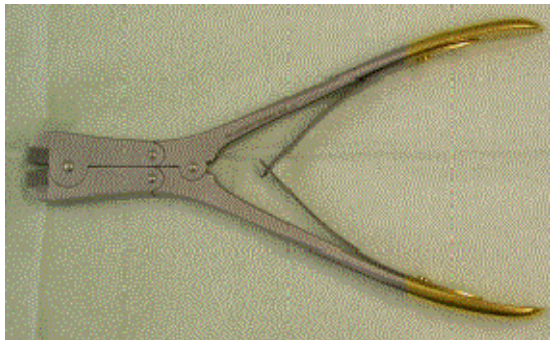
A: Crile-Clamp and similar hinge size, Box lock circa 7 x 14 mm



B: Box lock circa 12 x 20 mm



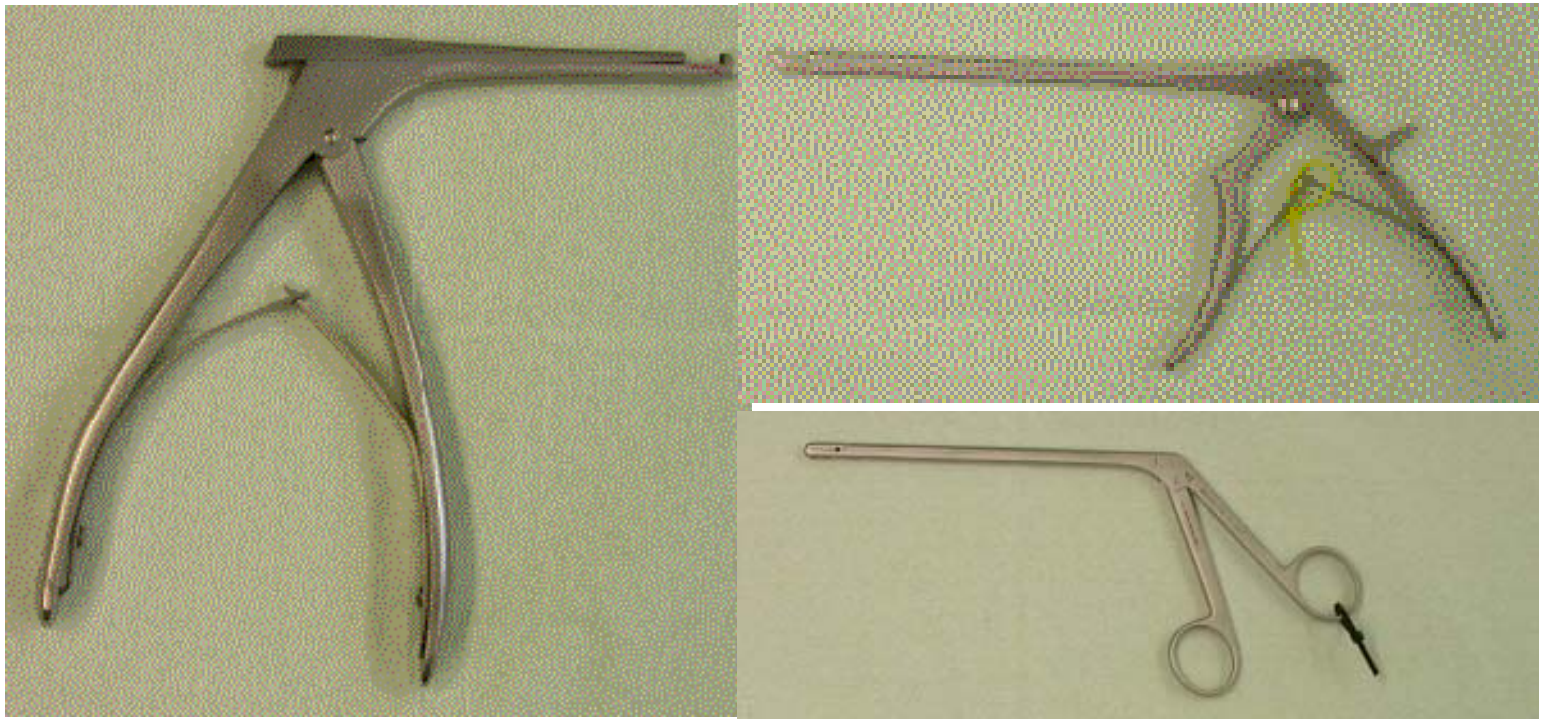
C: Box lock circa 16 x 25 mm



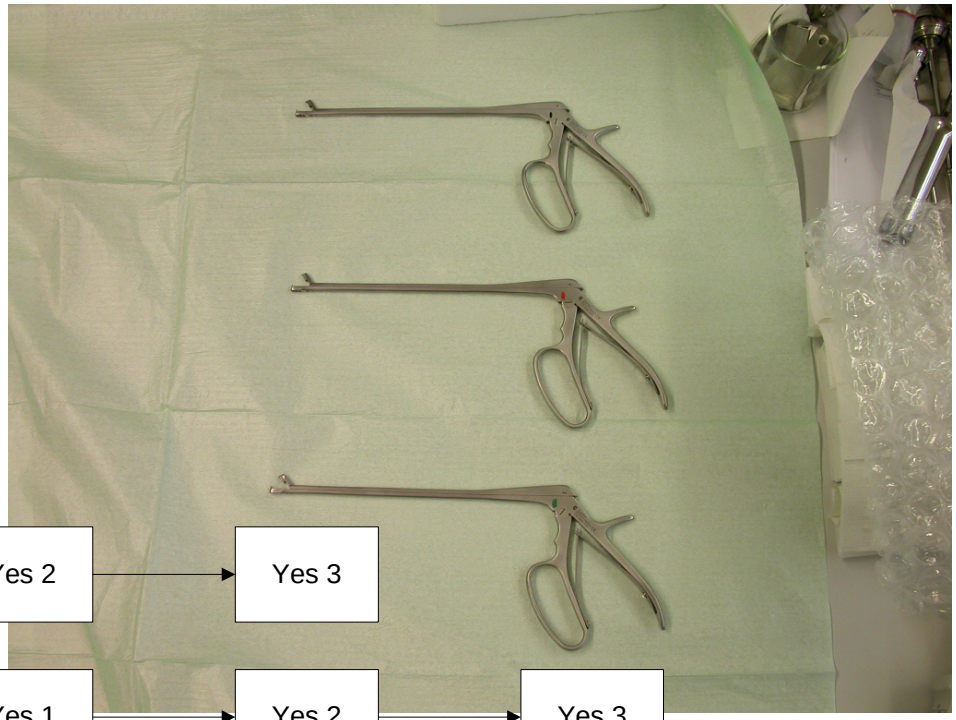
Group 3 (Shift shaft instruments):
Rongeur, Arthroskopiezangen etc.

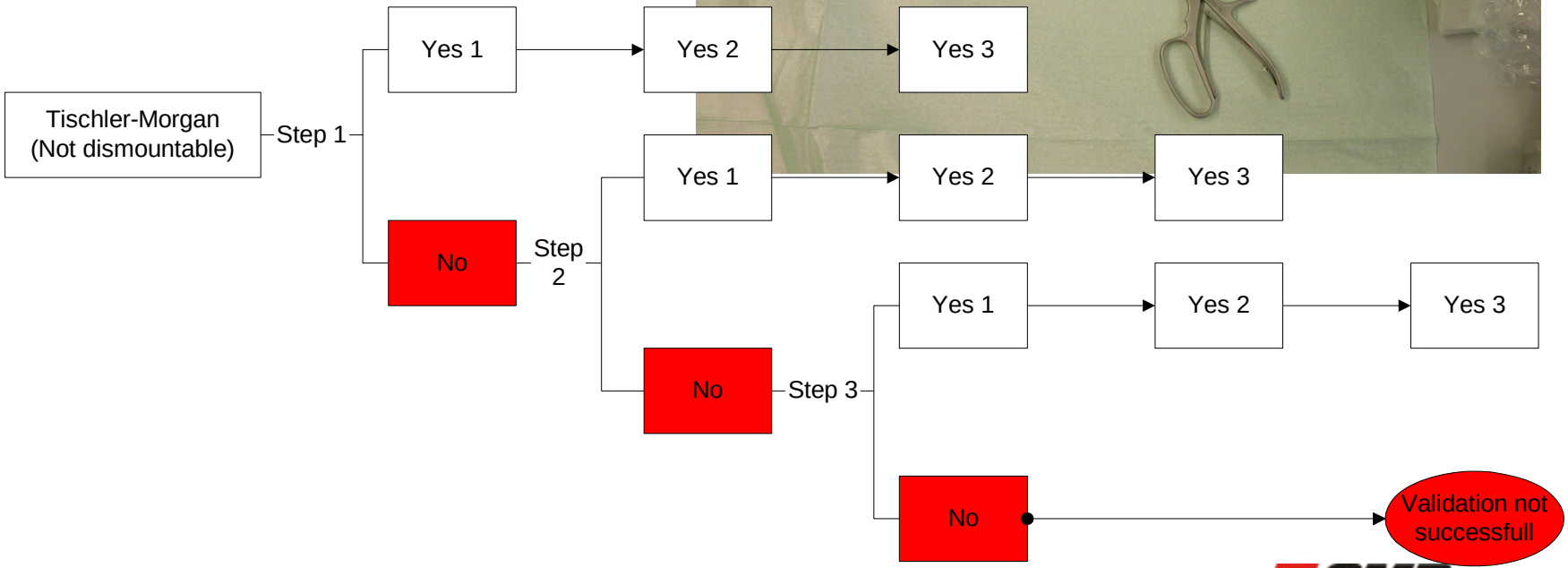
Subclassification:

Category A up to 3 mm diameter
Category B 3 to 5 mm
Category C bigger than 5 mm



Group 3: Shift shaft instruments



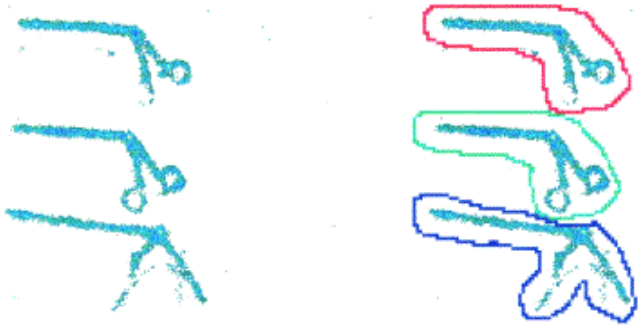


Group 3 (Shift shaft instruments): Rongeur,Arthroskopiezangen etc.

SMP GmbH - Service für Medizinprodukte
Paul-Ehrlich-Strasse 40 72076 Tübingen Tel: 07071/770 42 43 Fax: 07071/770 42 44

88/06 *00.00.2000
Datum:07.09.2006 11:00 9 MBq Tc-99m

ROI-Auswertung



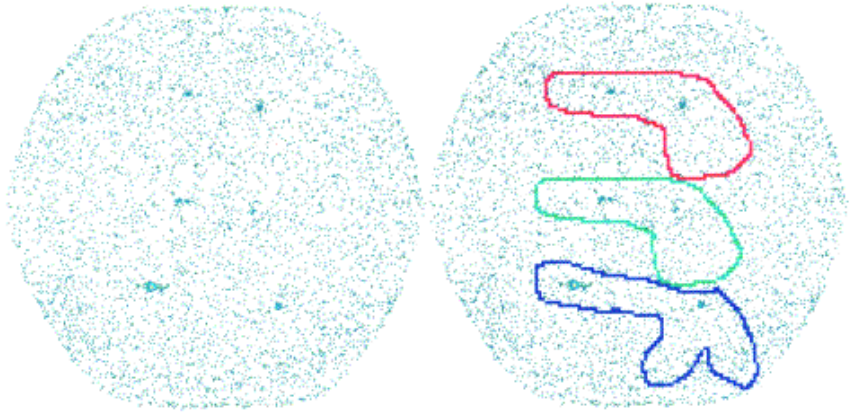
Ergebnisse der ROI-Auswertung

ROI-Name	Impulse	Pixel	Imp/Pixel	Imp/Sec	Imp/Pixel/Sec
Arthro S	13432	4571	2,94	89,546669	,019590
Arthro R	16734	4573	3,66	111,559998	,024395
Arthro G	13273	4791	2,77	88,486664	,018469

SMP GmbH - Service für Medizinprodukte
Paul-Ehrlich-Strasse 40 72076 Tübingen Tel: 07071/770 42 43 Fax: 07071/770 42 44

88/06 *00.00.2000
Datum:07.09.2006 14:28 9 MBq Tc-99m 17

ROI-Auswertung

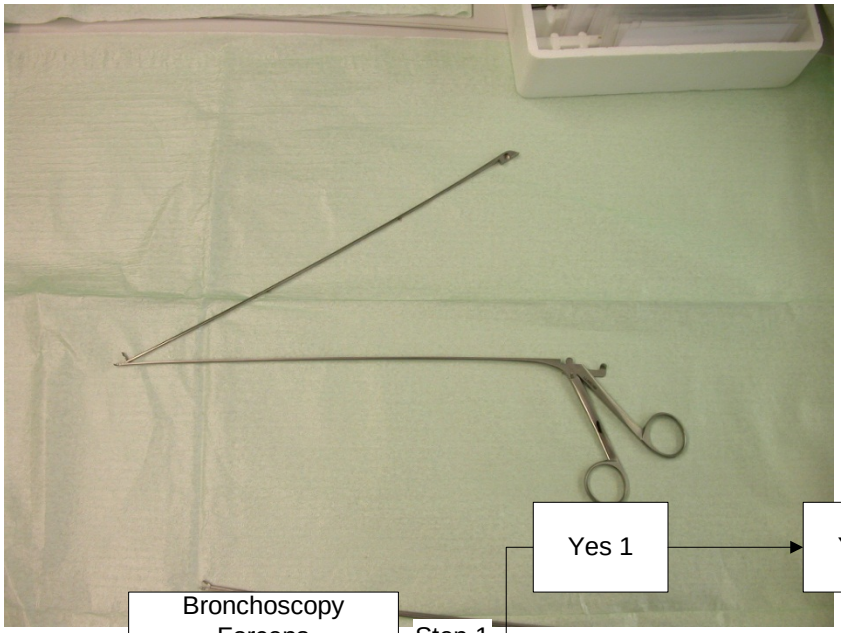


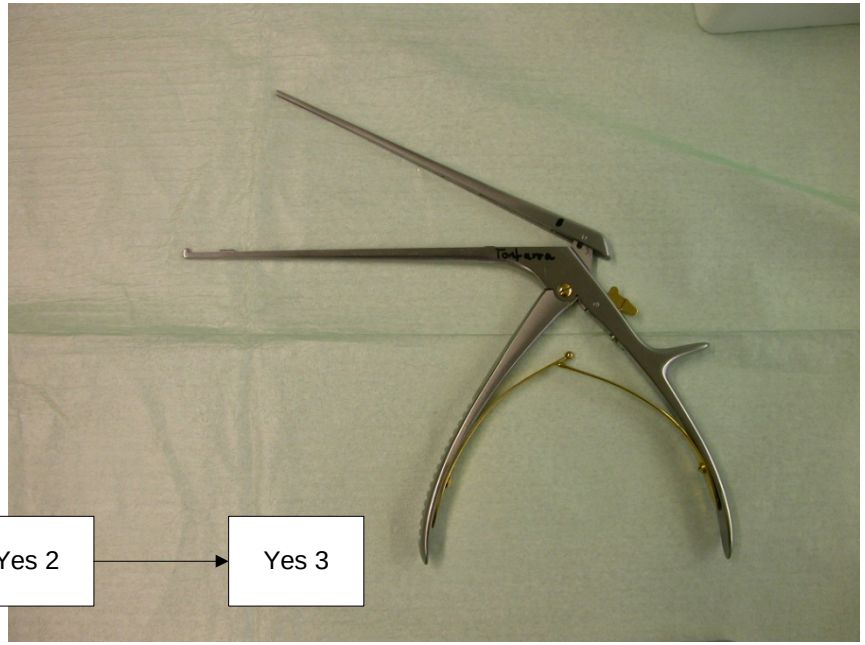
Ergebnisse der ROI-Auswertung

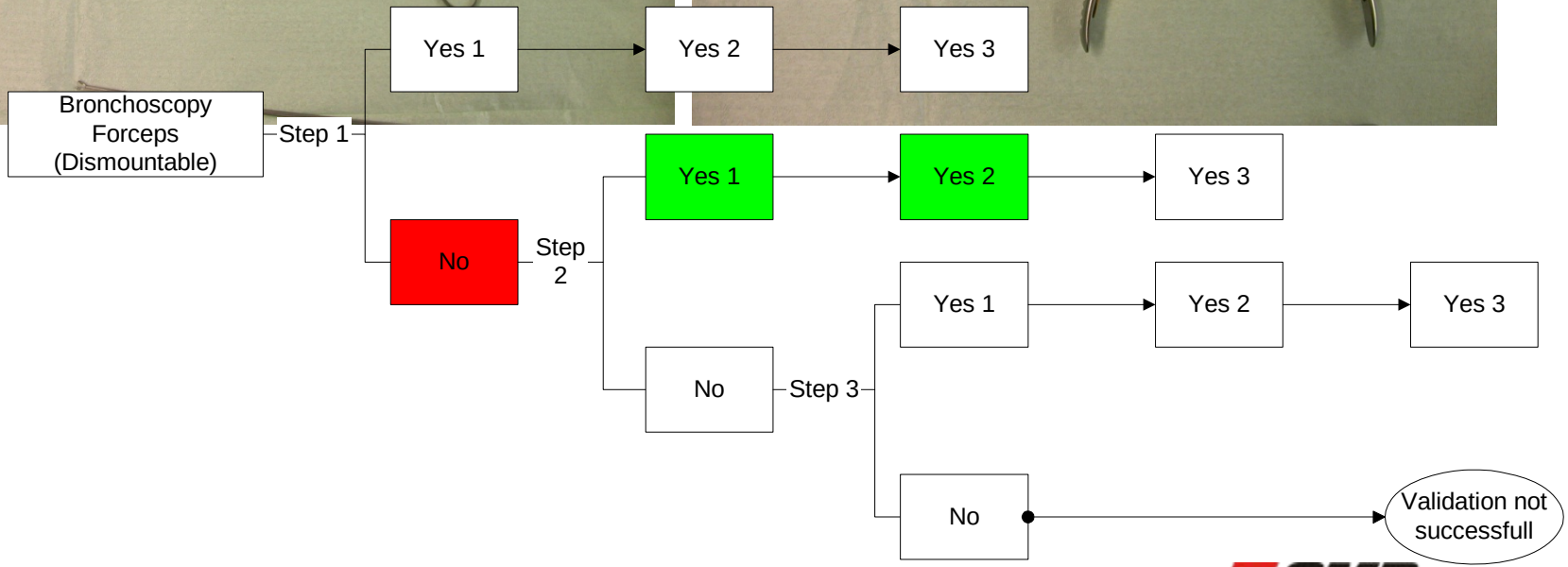
ROI-Name	Impulse	Pixel	Imp/Pixel	Imp/Sec	Imp/Pixel/Sec
Arthro S	490	4571	,11	3,266667	,000715
Arthro R	468	4573	,10	3,120000	,000682
Arthro G	877	4791	,18	5,846667	,001220

Nr.87/26	Zr	Zr	Zr		Zr	Zr	Zr	
	1. Messung nach Kontamination	2. Messung nach Vorreinigung + 10 min 40°C Einweichen	4. Messung nach Reinigung		1. Messung nach Kontamination	2. Messung nach Vorreinigung + Ultraschall 10 min 40°C	3. Messung nach Reinigung	
Rongeur 1	85	14	16		249	13	7	
Rongeur 2	121	11	10		311	12	7	
Rongeur 3	88	17	17		245	30	17	

Group 3: Shift shaft instruments (dismantable)







Influence of the detergent

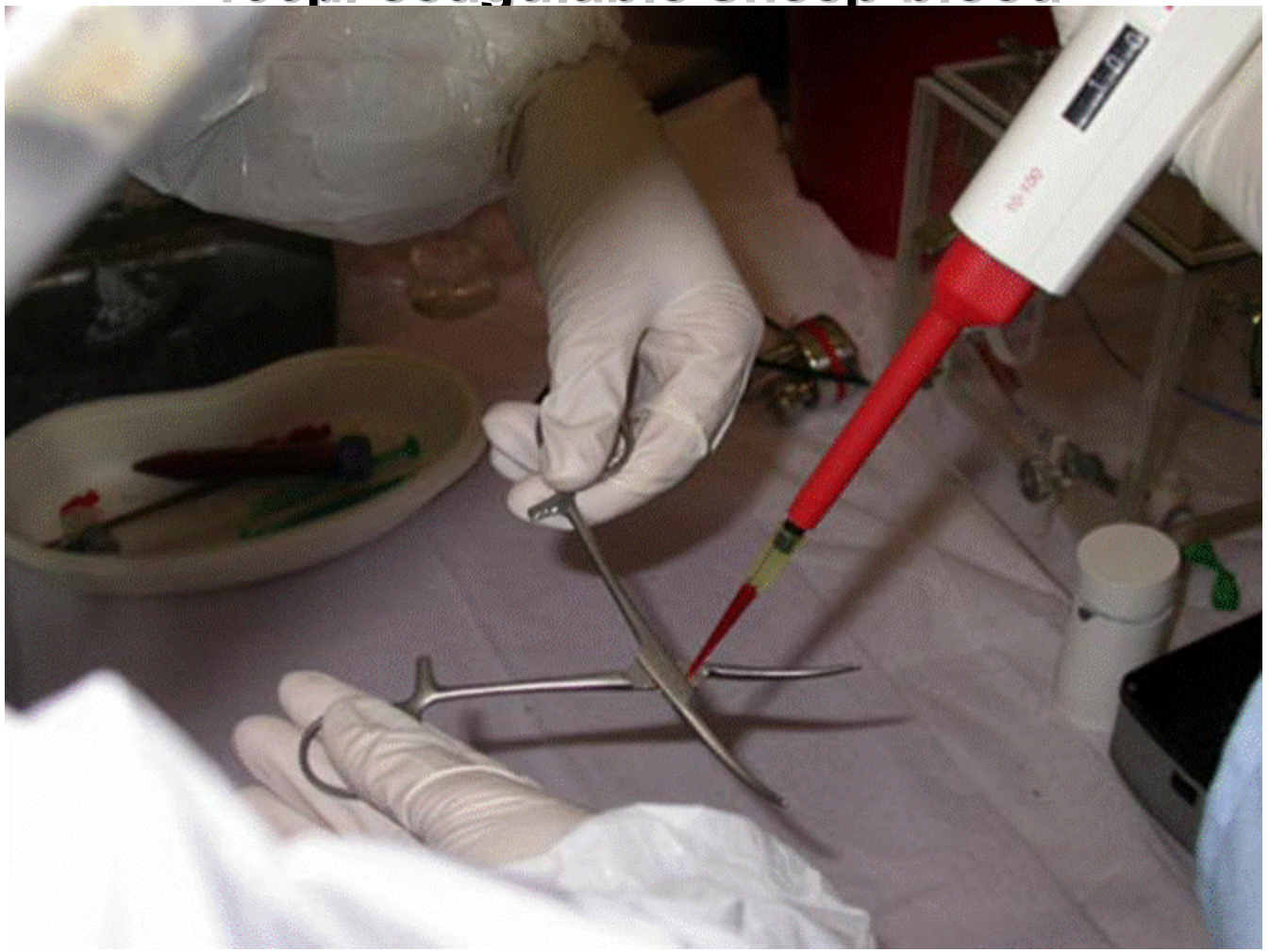
Group 2: Alkaline								
Effort for cleaning	Step 3							
	Step 2							
	Step 1							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E	2 F
		Instruments sorted by category						

Tab. 58: Zusammengefasste Ergebnisse Gruppe 2 „Alkalisch maschinell und ggf. manuellen Vorreinigung“

Group 2: Enzymatic automated and manual if necessary								
Effort for cleaning	Step 3				Validation not successfull			Validation not successfull
	Step 2							
	Step 1							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E	2 F
		Instruments sorted by category						

Tab. 59: Zusammengefasste Ergebnisse Gruppe 2 „Enzymatisch maschinell und ggf. manuelle Vorreinigung“

Cleaning: Contamination of the artery clamps with 100µl coagulable sheep blood



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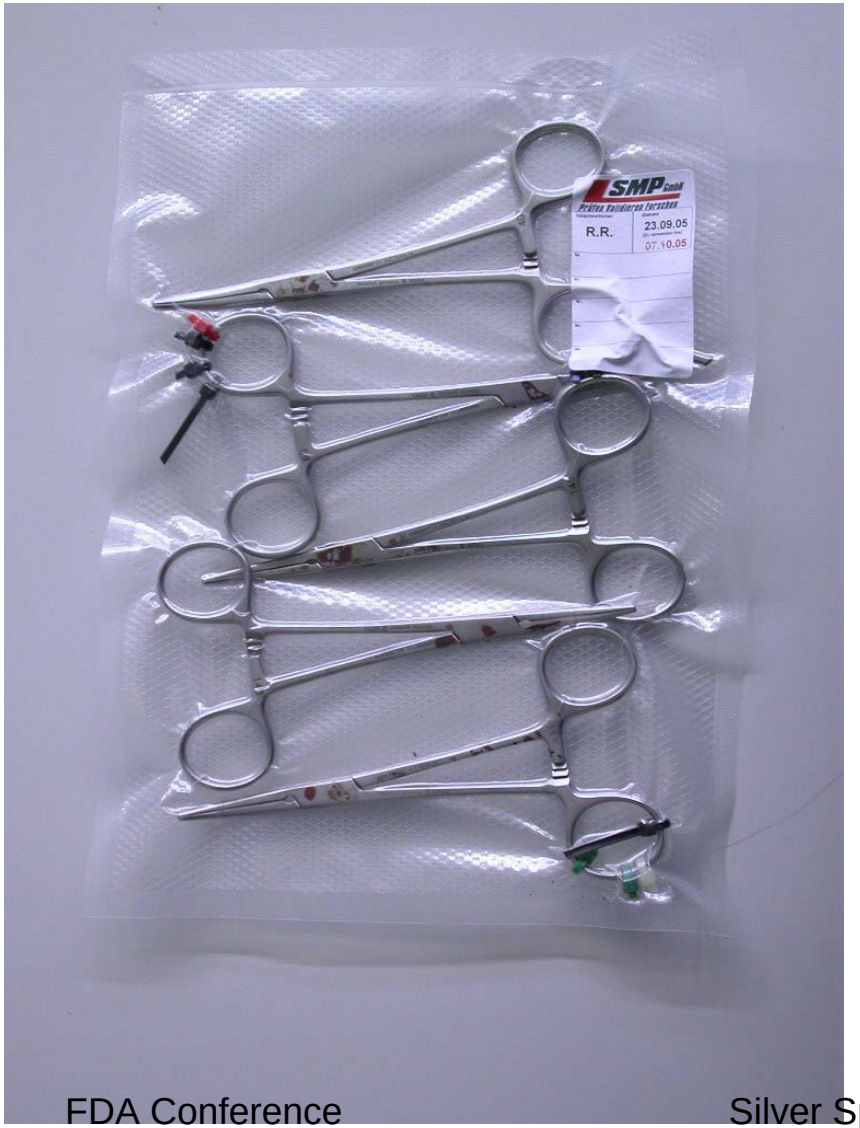
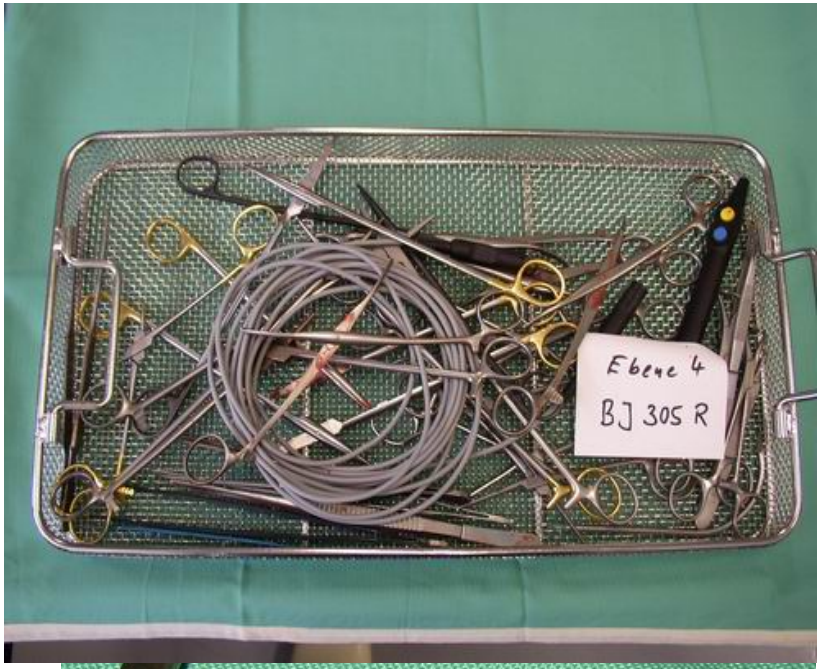
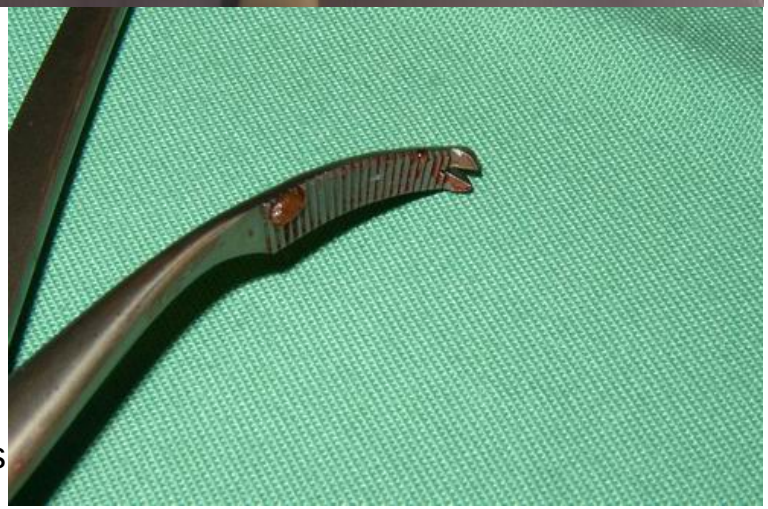
Validation of Washer/Disinfectors (Cleaning tests)

PCD: Vacuum package

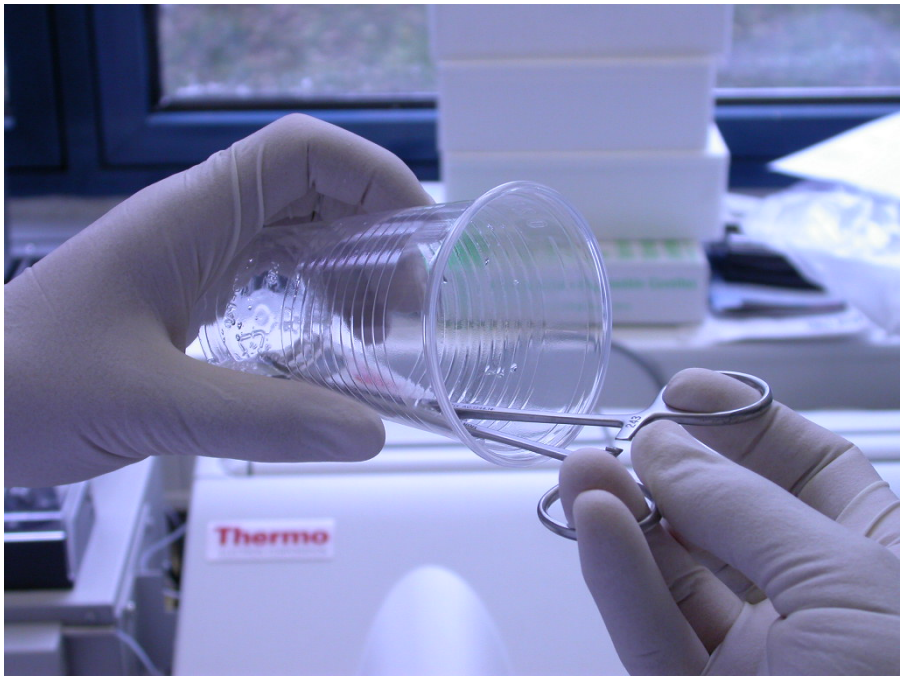


Real contamination



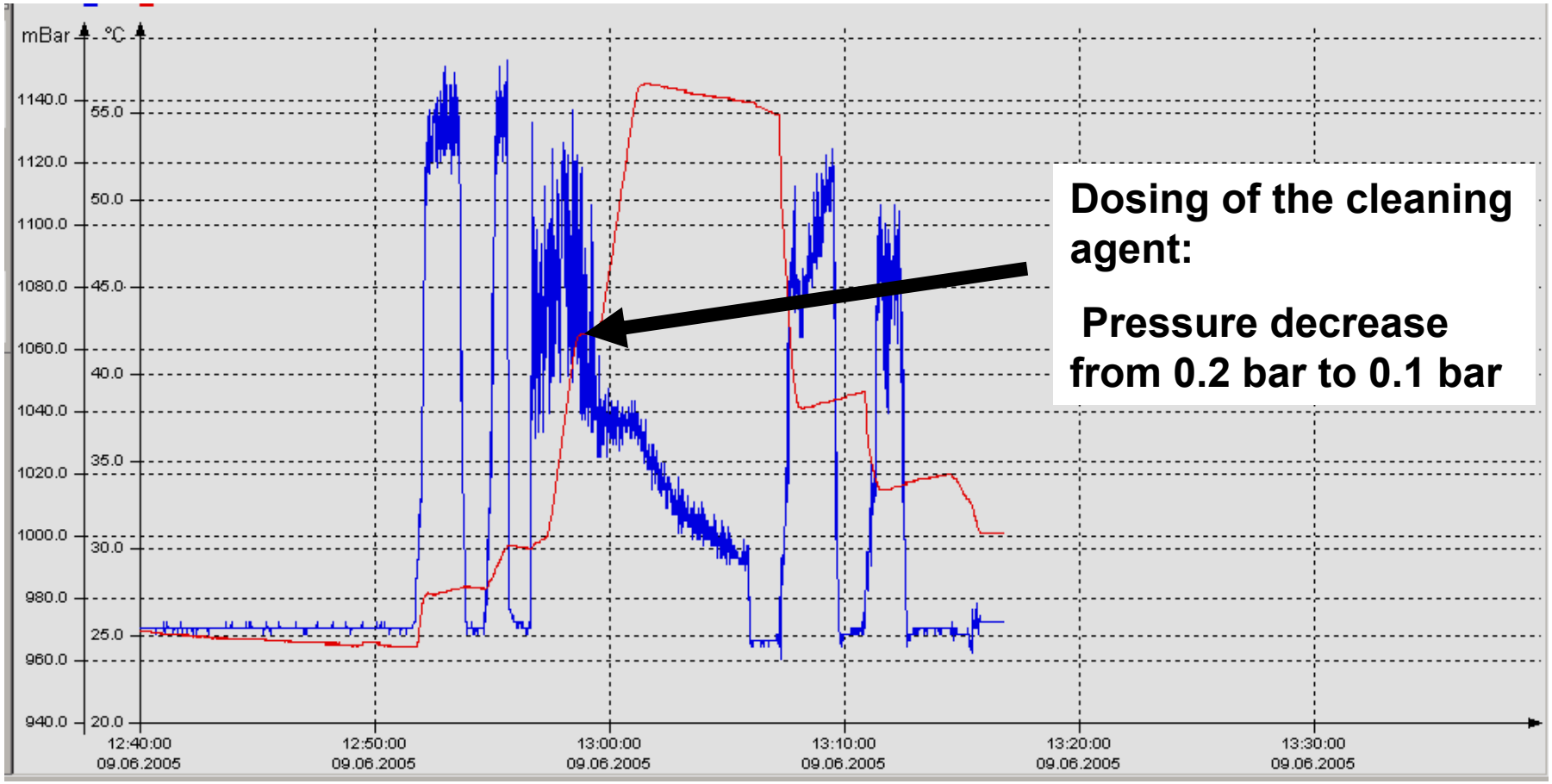


SDS-Elution for OPA-testing

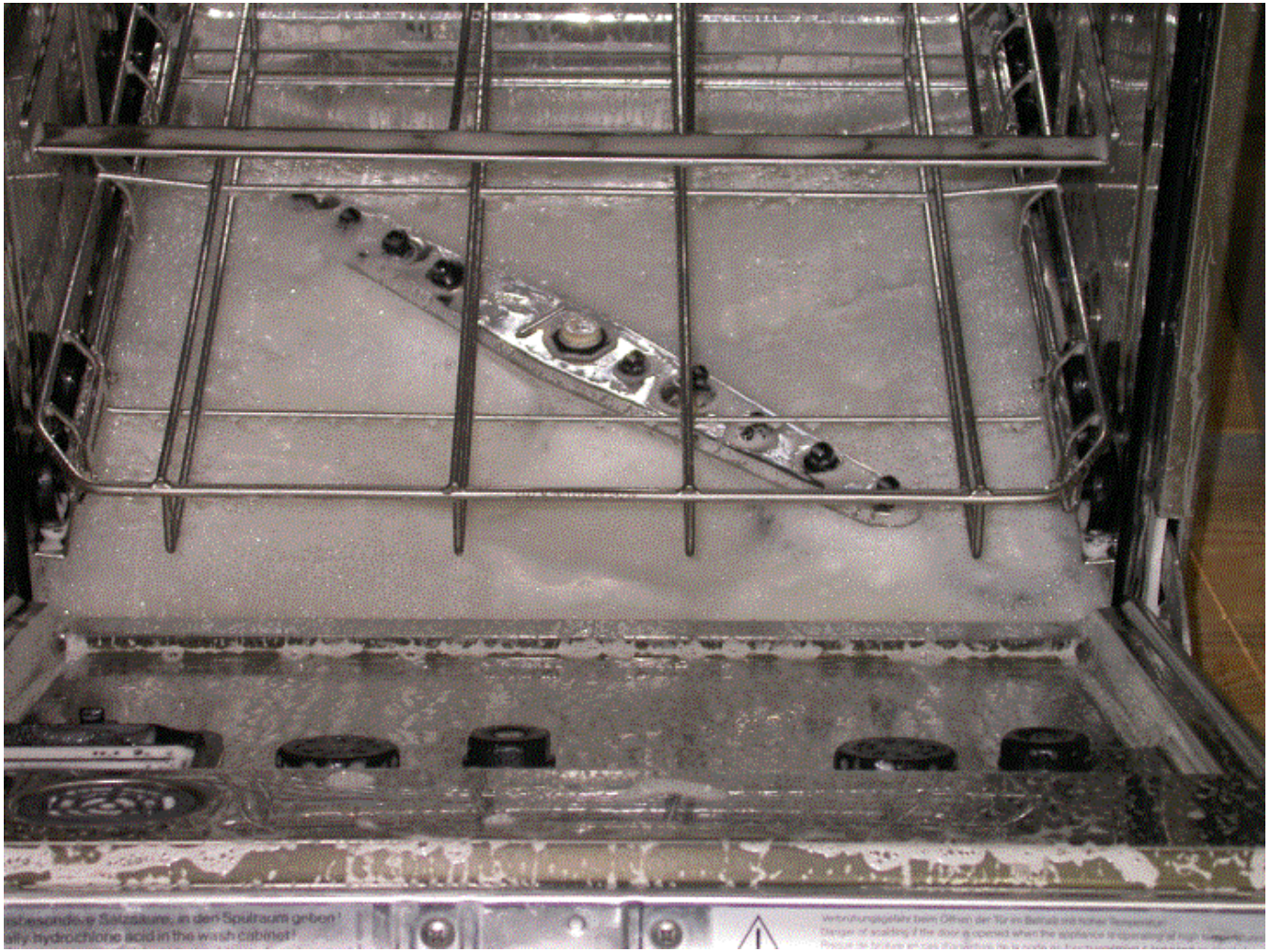


Foaming in the cleaning process

Logger data in a washer/disinfector loaded with heavily soiled instruments



Foaming



Products:	Endoscopic Take-Apart Instrument / Company:…….	
ADVICE:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.	
Reprocessing Instructions		
Preparation at the Point of Use:	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.	
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.	
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state.	
Pre-Cleaning:	**Warning: Do not allow the instruments to rest on the bottom of an ultrasonic cleaner unit during cleaning, as damage or incomplete cleaning could result.** 10 minutes at 40°C in an ultrasonic bath with 0,5% detergent. Brushing the instrument under running tap water until all visible residues are removed Flushing the inner lumens of all parts with a water jet pistol (pressure min. 3 bar) with cold tap water for at least 10 seconds.	
Cleaning:	Manual Cleaning Process: 1. Rinsing under running tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove visible soil; 2. Submerge instruments in an detergent (if ultrasonic bath is used, ultrasonic process of 3 minutes and ultrasonic frequency of 35 kHz have been shown to be effective). Follow the instructions of the manufacturer of the detergent; 3. Rinse the instrument under running tap water to remove the detergent.	Automated Cleaning: Connect the instrument to a rack for MIS-instruments and start the program • 4 min pre-washing with cold water (<40°C); • 6 min washing with 0,5% detergent at 55°C; • 3 min neutralising with warm water (>40°C); • 2 min intermediate rinsing with warm water (>40°C). Special instructions of the manufacturer of the automated washing machine have to be followed.

Disinfection:	Manual Disinfection: 1. Submerge instruments in an disinfection detergent according to the instructions of the manufacturer of the detergent; 2. Rinse the instrument with sterile water to remove the detergent.	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A_0-Value (see EN 15883)
Drying:	Manual Drying: Dry the instrument with a lint free towel. The instrument may never be heated up >140°C. To avoid water residues we recommend using sterile compressed air to insufflate cavities.	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Functional testing, if available according to instructions of use and visual inspection for cleanliness. If necessary perform reprocessing process again until instrument is visibly clean.	
Packaging:	Appropriate packaging for sterilization.	
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum process (according DIN EN 554 / ISO 11134) under consideration of the respective country requirements. **Parameters for the pre-vacuum cycle:** 3 prevacuum phases with at least 60 milli bar Heat up to a minimum sterilization temperature of 132°-134°C Minimum Holding time: 3,5 min Drying time: minimum 10 min **Flash sterilization is not allowed on lumen instruments!**	
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.	
Reprocessing validation study information	The following testing test devices, materials & machines have been used in this valdition study; Detergent: deconnex 28 Alka One, (Borer, Zuchwil, Switzerland) deconnex 23 Neutrazym, (Borer, Zuchwil, Switzerland) Washer / Disinfector: Miele 7735 CD Instrument Rack: Miele E450-1 Details: See report SMP 05506011407-1	

Conclusion

Different test method needs different markers.

Coagulable Blood seems to be the most realistic test soil, especially when the test method is able to detect fibrin.

RNM and OPA method correlates to some extend

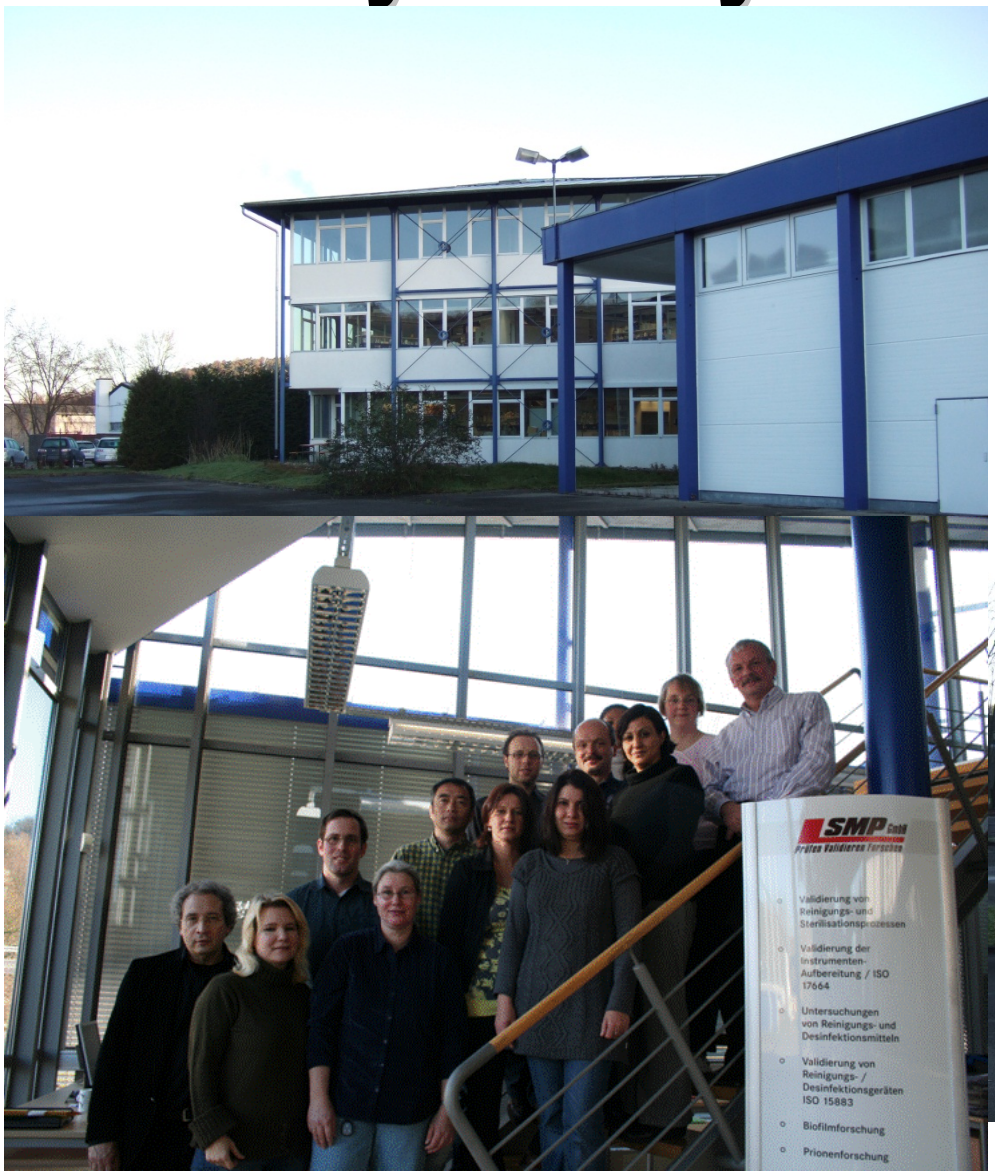
The spatial resolution of RNM allows a risk analysis

RNM can also be used as a quality control for elution test methods

Alcaline detergents lead to better cleaning results than enzymatic processes.

Check what kind of information are available from the manufacturer. It is important to analyze the reprocessing behavior before purchasing new instruments.

Thank you for your attention



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